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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,689

03/31/2004

Anthony D. Cristillo

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11/16/2006

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

599 LEXINGTON AVENUE, 29TH FLOOR

NEW YORK, NY 10022-7650

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/814,689	Applicant(s) CRISTILLO ET AL.	
	Examiner Louise Humphrey, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-24 are pending, of which claims 1-12 are under examination and claims 13-24 are withdrawn from consideration.

The rejection of claims 1-12 under 35 U.S.C. §102(b) as being anticipated by Huang *et al.* (1995) **is withdrawn** in view of Applicants' argument that the reference teaches a substitution mutation instead of the claimed deletion mutation of the viral budding mediating motif.

The rejection of claims 1-7 and 10-12 under 35 U.S.C. §102(b) as being anticipated by Craven *et al.* (1999) **is withdrawn** in view of the Applicants' argument that the reference teaches a substitution mutation instead of the claimed deletion mutation of the viral budding mediating motif.

Applicant's arguments, filed on 28 August 2006, with respect to the rejection(s) of claims 1-12 under 35 U.S.C. §102(b) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made in view of the "deletion mutation" limitation that has not been addressed in the previous Office Action.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Xiang *et al.* (1996).

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The instant invention is a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a viral protein encoded by the nucleic acid, wherein the viral protein is associated with the virus budding process.

Xiang *et al.* teach deletion mutations of the highly conserved amino acids, PPPPYV, of the p2b region in the Rous sarcoma virus Gag protein. The deletions removed just the conserved sequence or small groups of amino acids flanking either the amino terminus or the carboxyl terminus of the PPPPYV motif, which resulted in a 90% decrease of viral budding. See Abstract and page 5696, especially Figure 1A. The DNA constructs of the deletion mutations were made by PCR with mutagenesis primers as listed in Table 1 on page 5698.

Thus, the instant invention is anticipated by Xiang *et al.*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Huang *et al.* (1995, filed IDS) in view of Xiang *et al.* (1996).

The instant invention is further limited to comprise additional nucleic acids, each encoding an additional viral protein.

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Huang *et al.* describe a HIV-1 molecular clone comprising of nucleic acids encoding HIV-1 Pol, Env, Rev, Tat, Nef and Gag, with substitution mutations of the PTAP motif in the Gag p6 region. Huang *et al.* do not disclose deletion mutations of the viral budding mediating motif.

Xiang *et al.* suggest making deletion mutation of the viral budding motif as set forth above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Huang *et al.* by making deletion mutation of the budding motif as taught by Xiang *et al.* The skilled artisan would have been motivated to do so to prevent viral budding and maturation in order to make noninfectious immature virus particles that can generate immune responses yet do not cause infection. There would have been a reasonable expectation of success, given the 10% budding observed with the deletion mutants and that substitution of heterologous amino acid sequences for the RSV L domain results in the concomitant rescue of budding of virus particles and CA maturation, as taught by Xiang *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

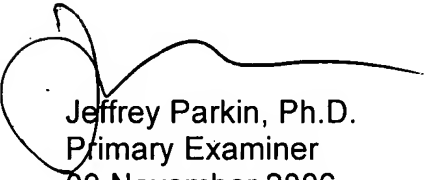
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**Contact Information**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
09 November 2006

*JWA*  
11/9/2006